

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA**

LINDA L. KITZMILLER and
RICHARD C. KITZMILLER, her husband,

Plaintiffs,

v.

Case No 2:05-CV-22

JEFFERSON SUPPLY COMPANY,

Defendant

ORDER/OPINION

On the 22nd day of June, 2006, Plaintiffs filed their “Motion to Strike Medical Causation Opinions of Michael J. Wernke, R.PH. and PH.D. Because he is not Qualified as a Medical Doctor to Express Medical Causation Opinions.” [Docket Entry 167]. On the 6th day of July, 2006, Defendant filed its “Response in Opposition” to Plaintiffs’ Motion [Docket Entry 179]. The undersigned finds the Motion is fully briefed and not complex and decides the issue without oral hearing.

In Plaintiffs’ Amended complaint, they allege, among others, that Defendant sold, furnished, and supplied chemical cleaning compounds, materials, and equipment to Plaintiff Linda Kitzmiller’s employer, the Grant County Board of Education, for use in cleaning its various school buildings. Plaintiffs allege Defendant breached its duty owed to Plaintiffs by negligently and carelessly failing to use reasonable care in providing mixing equipment and toxic chemicals for use in the Maysville School when it knew, or should have known, that the said Maysville School building was unventilated or poorly ventilated and that such toxic cleaning agents were only to be used in well-ventilated areas; by installing the “command center” in a janitor’s supply closet, a completely unventilated area; and by failing to routinely check and maintain the “command center” to insure

it was functioning properly and that the toxic cleaning agents were being routinely mixed and dispensed properly. Plaintiffs allege that as a proximate cause of the aforesaid alleged breach of duty, Plaintiff Linda Kitzmiller was exposed to said toxic chemicals and suffered severe and permanent injuries and illness, including but not limited to severe and chronic respiratory problems, acute chemical sensitivity, and nerve damage.

On February 13, 2006, Defendant filed its Expert Witness disclosure, disclosing Michael J. Wernke, R.Ph., Ph.D., a toxicologist/pharmacologist. In his Report, Dr. Wernke wrote, in pertinent part:

I have reviewed the materials you provided me using the criteria of the scientific method. Although various criteria have been advanced, such as the nine criteria commonly referred to as the Hill criteria, I believe these nine criteria can be distilled into the following six: (1) evidence of a completed exposure pathway; (2) evidence that the individual was exposed to, and/or received a dose of a chemical capable of causing the alleged ailment; (3) evidence in the available medical and scientific literature demonstrating that the chemical is capable of causing the alleged ailment particularly at the level to which the individual was exposed; (4) a temporal relationship between exposure and onset of the alleged ailment; (5) elimination of other possible causes of the alleged ailment; and (6) a biologically plausible mechanism, firmly ground in scientific investigation, by which the chemical causes the alleged ailment. It is against these criteria that I have evaluated this matter.

There is no objective evidence upon which to base an opinion that Ms. Kitzmiller's use of Blue Skies and/or Bathmate, the products specifically identified by Ms. Kitzmiller and Mr. Petty,¹ or her alleged exposure to benzalkonium chloride, the specific constituent of Blue Skies and Bathmate identified by Mr. Petty, caused Ms. Kitzmiller's reported respiratory ailment (BOOP).² No evidence has been advanced demonstrating that Ms. Kitzmiller was in fact exposed to benzalkonium chloride in the air of her workplace at all, let alone at levels capable of causing harm. While Mr. Petty placed considerable emphasis on the fact that some of the products Ms. Kitzmiller reportedly used contained benzalkonium chloride, he provided no objective evidence as to the airborne level of exposure, if any, she incurred as a result of her use of these products. The mere fact that Ms. Kitzmiller reportedly used

¹Mr. Petty is one of Plaintiffs' disclosed experts.

²Bronchiolitis obliterans organizing pneumonia.

products containing benzalkonium chloride does not provide any objective proof whatsoever of a complete exposure pathway or receipt of a dose of these compounds capable of causing harm. It is clear from her own deposition that Ms. Kitzmiller did not have physical contact with these products, and in fact wore gloves while using them (Kitzmiller deposition, pages 80 and 102). Moreover, Ms. Kitzmiller testified that while using these products she experienced no adverse health effects, such as skin, eye, nose, or throat irritation. Therefore, there is simply no objective evidence whatsoever that Ms. Kitzmiller was exposed to, or received a dose of benzalkonium chloride contained in Blue Skies or Bathmate at all, let alone at levels capable of causing harm.

In his two reports, Mr. Petty stated that benzalkonium chloride has been associated with BOOP. His support for that statement appears to rest on a single case report by Di Stefano et al. (2003). This case report, however, does not provide a reliable basis for concluding that benzalkonium chloride is a cause of BOOP. Di Stefano et al. (2003) describe a woman who “spilled on the floor a large amount of a cleaning agent which she was pouring into the container of a floor-polisher, inhaling its vapours. The components of this cleaning agent turned out to be benzalkonium compounds, a group of biocides with the general formula alkyl-dimethyl-benzyl-ammonium-chloride” (page 182). Di Stefano et al. (2003) go on to report that immediately following the spill this woman experienced a dry cough and burning eyes which made her stop working. Shortly thereafter she was reportedly diagnosed with BOOP. Interestingly, Di Stefano and coworkers (2003) also noted that their case’s neutrophils were deficient of the enzyme myeloperoxidase. While the authors of this case report advance their belief that exposure to benzalkonium chloride had a causative role in the pathogenesis of their case’s respiratory ailment (BOOP), they also raise the possibility that her neutrophilic myeloperoxidase deficiency too may have been a factor in the onset of her reported ailment, and noted that “further observations are necessary to establish if this defect in the formation of neutrophil granules was a causal finding in the reported case of BOOP, or was concomitant cause together with the incidentally heavy exposure to benzalkonium compounds” (page 183).

Case reports do not constitute scientific evidence of a cause and effect relationship. Because of their nature – the reliance on an author to accurately report their findings (hence the possibility of investigator bias cannot be excluded), the lack of any statistical analysis of data, and the lack of a control group, to name a few of their deficiencies – case reports constitute the lowest form of scientific evidence. At best, case reports are hypotheses generating (i.e., may stimulate further research); they are clearly not hypotheses testing studies (they cannot confirm or refute a cause and effect relationship). In this particular case report the authors do not provide any objective evidence of the volume of the “large amount of cleaning agent” spilled or the concentration of benzalkonium chloride in the vapor reportedly inhaled by their subject. In fact, they even fail to report the concentration of the benzalkonium

chloride in the product that was spilled. Hence, there is no objective means to confirm their reported findings. Moreover, the description of events provided by Di Stefano et al. (2003) does not in any way resemble that which is described in this particular matter. Specifically, Ms. Kitzmiller did not report spilling a “large amount of cleaning agent,” did not have immediate symptomology causing her to stop working after using Blue Skies or Bathmate (i.e., lack of a consistent temporal relationship), and she did not have neutrophils deficiency in myeloperoxidase (West Virginia University Hospital, 10/11/04; Dr. Martin IME dated 10/11/04). Similarly, because of the lack of information provided by Di Stefano et al. (2003), one does not know whether the concentration of benzalkonium chloride in the product spilled by the case described by these authors was similar to that in found in the Blue Skies or Bathmate used by Ms. Kitzmiller. Given the fact that benzalkonium chloride can be found in numerous products, including medications (such as inhalers used in the treatment of asthma), cosmetics, cleaning products, disinfectants, shampoos, eye drops and contact lens solution, to name a few, the lack of any other report or epidemiological study of BOOP associated with products containing benzalkonium chloride calls into question the reliability of the report published by Di Stefano and coworkers (2003) and their expressed beliefs. Simply put, the case report by Di Stefano et al. (2003) is unverified and hence unreliable, and as such it does not provide a scientific basis for concluding that benzalkonium chloride is a cause of BOOP.

Other possible causes of Mr. Kitzmiller’s alleged complaints, in particular infection, have not been eliminated as the cause of her reported respiratory ailment (BOOP). Indeed, various medial entries, such as those from Grant Memorial Hospital dated November 6, 2002, Sacred Heart Emergency Room dated November 19, 2002, and Dr. Schmitt dated November 26, 2002 and December 16, 2002, all note the onset of an upper respiratory tract infection or cold beginning in early October of 2002. Infection has been associated with BOOP. Clearly, Ms. Kitzmiller’s reported upper respiratory tract infection occurring in early October 2002, is a potential cause of her reported respiratory ailment that has not been eliminated. Hence, this criterion of the scientific method has not been fulfilled.

Finally, there is no biologically plausible mechanism, firmly ground by scientific investigation, by which exposure to benzalkonium chloride could cause BOOP in humans. Indeed, no studies have been performed in humans, animals, isolated lungs or cellular constituents of the lungs demonstrating that exposure to benzalkonium chloride ultimately leads to pathology in the terminal airways such as that seen in BOOP.

Therefore it is my opinion to a reasonable degree of scientific certainty that Ms. Kitzmiller’s use of Blue Skies and Bathmate while employed by the Grant County School System did not cause her alleged respiratory ailment, reportedly identified as

BOOP.³

Plaintiff refers to the above report as containing a “a long list of medical causation opinions,” and argues that “Dr. Wernke, without the benefit of the minimum qualifications of even a family practitioner, and with no certifications or even license as a medical doctor is not qualified to treat a patient or render any medical advice whatsoever” and “Medical causation opinions by a witness who does not possess the required medical degree and attendant specializations and certifications are simply not allowed.”

The Fourth Circuit holds:

Unlike evidentiary rules concerning burdens of proof or presumptions, the admissibility of expert testimony in a federal court sitting in the diversity jurisdiction is controlled by federal law.

Scott v. Sears, Roebuck & Co., 789 F.2d 1052 (4th Cir. 1986).

Federal Rule of Evidence 702 provides:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Plaintiffs do not, in this motion, question the facts, data, principles or methods that form the basis of Dr. Wernke’s opinion, or its reliability (typical *Daubert* challenges). Instead Plaintiffs argue Dr. Wernke, a pharmacologist/toxicologist but not a medical doctor, is not qualified to testify

³Dr. Wernke supplemented his report on May 8, 2006, again opining “to a reasonable degree of scientific certainty,” that Plaintiff’s use of Blue Skies and Bathmate while employed by the Grant County Schools did not cause her alleged respiratory ailment, reportedly identified as BOOP.

as to causation. Plaintiffs expressly state: “There is a wealth of authority that supports this Motion,” citing only Plourde v. Gladstone, a 2002 case out of the District of Vermont. 190 F. Supp. 2d 708. In Plourde a toxicologist intended to testify that certain herbicides caused the plaintiff’s injuries. The court held that the toxicologist expert witness failed to satisfy the qualifications requirement under Rule 702 because he was not a medical doctor. His lack of appropriate qualifications also was held to invalidate his attempt to rely on medical doctors’ opinions, because he did not offer any proof that toxicologists regularly rely on opinions and diagnoses of trained doctors and veterinarians as to causation.

Neither party cites, and the undersigned could not locate, a Fourth Circuit case on point. At least two Federal Courts of Appeal have held that toxicologists may testify as to causation, however. In Paoli Railroad v. Monsanto Co., et al., 915 F.2d 829 (3rd Cir. 1990), the district court had excluded much of an expert’s testimony “on the grounds that she is neither a chemist qualified to present an opinion based on gas chromatography tracing nor a medical doctor qualified to present her opinion on what caused the plaintiff’s emotional and physical injuries.” The district court excluded another expert witness because he was “not trained in differential diagnosis.” The Third Circuit stated:

The district court’s insistence on a certain kind of degree or background is inconsistent with our jurisprudence in this area. The language of Rule 702 and the accompanying advisory committee notes make clear that various kinds of “knowledge, skill, experience, training, or education” . . . qualify an expert as such

The three experts the district court had excluded in Paoli included a toxicologist with a Ph.D. in Pathology; a Ph.D. in Microbiology; and a Ph.D. in Physics. The Third Circuit held:

In light of the liberal rule 702 expert qualification standard, we hold that the district court abused its discretion in excluding portions of [the experts’] testimony simply

because the experts did not have the degree or training which the district court apparently thought would be most appropriate.

Id. at 855-856.

In 1991, the Third Circuit revisited the issue in Genty v. Resolution Trust Corp., 937 F.2d 899 (3rd Cir. 1991). In Genty, the district court had excluded the proffered testimony of the plaintiff's expert, a toxicologist. The toxicologist was offered "to render the expert opinion that the plaintiffs' injuries could have been caused by exposure to the toxic chemicals present in the GEMS landfill." The toxicologist would "testify on the basis of what the plaintiffs [would] report as problems they had . . . that these are things caused by the substances emanating from the landfill." The expert was not a medical doctor and he had not examined the plaintiffs. The district court excluded the expert, stating that the plaintiffs had not "produced a medically qualified expert to testify about causation. Their proposed expert for physical injuries is a toxicologist, not a medical doctor." Id. The Third Circuit stated:

The only reason given by the trial court for the exclusion of Dr. Brubaker is that he was not a medical doctor. Medical doctors, however, are not the only experts qualified to render an opinion as to the harm caused by exposure to toxic chemicals. The trial court's exclusion of Brubaker, without considering his credentials as a doctor of toxicology, simply because he did not possess a medical degree, is inconsistent with expert witness jurisprudence.

Id.

The Eighth Circuit ruled similarly in a very recent case, Marmo v. Tyson Fresh Meats, Inc., - - - F.3d - -, 2006 WL 2165734 (8th Cir. Aug. 3, 2006). In Marmo, the district court had precluded a toxicologist from opining as to causation. The Eighth Circuit stated:

We have previously held that a toxicologist may testify that exposure to a chemical caused a person's symptoms and injuries. Bonner v. ISP Techs., Inc., 259 F.3d 924, 928-31 (8th Cir. 2001); Loudermill v. Dow Chem. Co., 863 F.2d 566, 569-70 (8th Cir. 1988); see also Reference Manual on Scientific Evidence 401-31 (2d ed. 2000)

(recognizing that toxicologists may offer expert opinions on whether exposure to a chemical caused an individual's injury.)

The undersigned finds the Third and Eighth Circuit cases well-reasoned and instructive. Dr. Wernke has offered no opinion as to whether Plaintiff's diagnosis was correct or incorrect, nor could he. In fact, he based his opinion on the assumption Plaintiff did have BOOP, as diagnosed by her physicians. The undersigned does not find the opinions stated in Dr. Wernke's two reports or in his deposition were outside of his area of expertise. The undersigned does not address the substance of those opinions or the basis therefore (*Daubert* issues).

The undersigned therefore finds, as did the Third and Eighth Circuits, that a toxicologist, in this case, Dr. Wernke, "may offer expert opinions on whether exposure to [the] chemical[s] caused [Plaintiff's] injury." Id.

Plaintiffs' "Motion to Strike Medical Causation Opinions of Michael J. Wernke, R.Ph. and Ph.D. Because he is not Qualified as a Medical Doctor to Express Medical Causation Opinions" [Docket Entry 167] is therefore **DENIED**.

The Clerk of the Court is directed to send a copy of this Order to counsel of record.

DATED: August 25, 2006.

/s *John S. Kaull*

JOHN S. KAULL
UNITED STATES MAGISTRATE JUDGE

